

USSN - 08/591,651

with --27--.

In claim 48, replace "method" with --kit-- and "43" with --27--.

Please amend claims 8, 10, 11, 16, 32, 50, 51, and 52 as follows:

C<sup>1</sup>  
8 (amended). The [method] kit of claim [31] 59 wherein, following such instructions, the first administration is when the mammal is less than 28 days old.

10 (amended). The [method] kit of claim [21] 59 wherein, following such instructions, the shortest interval between two successive dosings of at least one immunogen is less than 28 days.

C<sup>2</sup>  
11 (amended). The [use] kit of claim [21] 59 wherein, following such instructions, during the first 175 days from birth the longest interval between two successive dosings of at least one immunogen is less than 28 days.

16 (amended). The [method] kit of claim [31] 59 wherein, following such instructions, said mammal is a human.

32 (amended). A method of reducing the incidence or severity of [an] a chronic immune-mediated disorder in a mammal which comprises administering to said mammal one or more immunogens, according to an immunization schedule by virtue of which the mammal receives, at ~~specific times after birth~~, one or more pharmaceutically acceptable doses of said immunogens, said administrations resulting in an immune response in said mammal which substantially reduces the incidence or severity of at least one chronic immune-mediated disorder in the mammal,

D  
C<sup>3</sup>  
the first dose of said immunization schedule being administered when the mammal is less than 42 days old, measured from birth,

where, if only one immunogen is administered according to said immunization schedule, that immunogen is one other than BCG, and, if said one immunogen is whole cell pertussis, the schedule is one other than a schedule of three doses at one week

C3  
C2  
intervals, all given in the first month,  
where, when all of the immunogens administered are selected from  
the group consisting of BCG, diphtheria, tetanus, whole cell  
pertussis, polio, hepatitis B, hemophilus influenza, measles,  
mumps and rubella immunogens, at least one of the following  
conditions applies: (a) one or more immunogens are administered  
on at least three different dates prior to 42 days after birth,  
or (b) one or more immunogens are administered on at least three  
different dates, and the maximum interval between administrations  
is about two weeks, or less.

F  
K  
C4  
50 (amended). The [method] kit of claim [8] <sup>43</sup>27 wherein,  
following such instructions, the first administration is when the  
mammal is less than 14 days old.

51 (amended). The [method] kit of claim [8] <sup>43</sup>27 wherein,  
following such instructions, the first administration is when the  
mammal is about 7 days old.

52 (amended). The [method] kit of claim [11] 27 wherein,  
following such instructions, the longest interval between two  
successive dosings is less than or about 14 days.

Please add the following new claims:

53  
C5  
--56. A method of reducing the incidence or severity of an  
immune disorder in a mammal which comprises administering to said  
mammal one or more immunogens, according to an immunization  
schedule by virtue of which the mammal receives, at specific  
times after birth, one or more pharmaceutically acceptable doses  
of said immunogens, said administrations resulting in an immune  
response in said mammal which substantially reduces the incidence  
or severity of at least one chronic immune-mediated disorder in  
the mammal,

the first dose of said immunization schedule being  
administered when the mammal is less than 42 days old, measured  
from birth,

where, if only one immunogen is administered according to

said immunization schedule, that immunogen is one other than BCG, where, when all of the immunogens administered are selected from the group consisting of BCG, diphtheria, tetanus, whole cell pertussis, polio, hepatitis B, hemophilus influenza, measles, mumps and rubella immunogens, at least one of the following conditions applies: (a) one or more immunogens are administered on at least three different dates prior to 42 days after birth, or (b) one or more immunogens are administered on at least three different dates, and the maximum interval between administrations is about two weeks, or less, and where one or more immunogens are administered on at least four different dates.

57. The method of claim 56 where one or more immunogens are administered on at least four different dates during the first 112 days after birth.

*CS Cont*  
58. The method of claim 56 where one or more immunogens are administered on at least four different dates during the first 42 days after birth.

59. A kit for use to protect a mammal against an infectious disease to which a mammal is susceptible, said kit comprising one or more containers, each container holding one or more pharmaceutically acceptable doses of one or more immunogens, at least one of said immunogens acting to protect against said infectious disease when appropriately administered to said subject,

said kit comprising labeling indicating

*Ans F2*  
(a) that the kit can be used to reduce the incidence or severity of a chronic immune-mediated disorder in a mammal, and providing instructions for the prophylactic or therapeutic use of said immunogens to reduce the incidence or severity of a chronic immune-mediated disorder in a mammal, said instructions stating that one or more doses should be administered according to an immunization

F2  
W schedule set forth in said instructions, said immunogens, when so administered, acting to substantially reduce the incidence or severity of said chronic immune-mediated disorder,

or

(b) that the kit, depending on when one or more of said immunogens is administered, may, can or does increase the incidence or accelerate the onset of a chronic immune-mediated disorder.

60. The kit of claim 59 where (a) applies.

61. The kit of claim 59 where (b) applies.

62. The kit of claim 61, said labeling further comprising instructions for administering such immunogens so as to avoid such increase in the incidence or severity, or such acceleration in the onset, of said chronic immune-mediated disorder.

C5  
Curt  
Sub  
F3 63. The kit of claim 59 wherein following such instructions the first administration is when the mammal is less than 14 days old.

64. The kit of claim 59 wherein following such instructions the first administration is when the mammal is about 7 days old.

65. The kit of claim 59 wherein following such instructions the longest interval between two successive dosings is less than or about 14 days.

F 66. The kit of claim <sup>43</sup>27 where at least one of said immunogens is a pediatric immunogen.

~~67. The kit of claim 66 where said pediatric immunogen is selected from the group consisting of BCG, measles, mumps, rubella, diphtheria, pertussis, hemophilus influenza, tetanus, hepatitis B, and polio immunogens.~~

F 68. The kit of claim <sup>43</sup>27 where at least one of said immunogens is a nonpediatric immunogen.

69. The kit of claim <sup>43</sup>68 in which said nonpediatric immunogen is selected from the group consisting of anthrax,

plague, encephalitis, meningococcal, pneumococcus, typhus, typhoid fever, streptococcus, staphylococcus, neisseria, lyme disease, cholera, E. coli, shigella, leishmania, leprosy, cytomegalovirus (CMV), respiratory syncytial, virus, Epstein Barr virus, herpes, influenza, parainfluenza, rotavirus, adenovirus, human immunodeficiency virus (HIV), hepatitis A, NonA NonB hepatitis, varicella, rabies, yellow fever, rabies, Japanese encephalitis, flavivirus, dengue, toxoplasmosis, coccidiomycosis, schistosomiasis, and malaria immunogens.

CS  
Cait  
F  
F  
F  
70. The kit of claim <sup>43</sup>27 in which at least one immunogen is selected from the group consisting of BCG, measles, mumps, rubella, diphtheria pertussis, hemophilus influenza, tetanus, hepatitis B, polio immunogens, anthrax, plague, encephalitis, meningococcal, meningitis, pneumococcus, pneumonia, typhus, typhoid fever, streptococcus, staphylococcus, neisseria, lyme disease, cholera, E. coli, shigella, leishmania, leprosy, cytomegalovirus (CMV), respiratory syncytial, virus, Epstein Barr virus, herpes, influenza, parainfluenza, rotavirus, adenovirus, human immunodeficiency virus (HIV), hepatitis A, NonA NonB hepatitis, varicella, rabies, yellow fever, rabies, Japanese encephalitis, flavivirus, dengue, toxoplasmosis, coccidiomycosis, schistosomiasis, and malaria immunogens.

F  
F  
F  
71. The kit of claim <sup>43</sup>27 in which at least one immunogen is selected from the group consisting of anthrax, plague, tetanus, pertussis, diphtheria, BCG, hemophilus influenza <sup>ant</sup> or smallpox immunogen.

F  
72. The kit of claim <sup>16</sup>59 where at least one of said immunogens is a pediatric immunogen.

BIO  
73. The kit of claim 72 where said pediatric immunogen is selected from the group consisting of BCG, measles, mumps, rubella, diphtheria, pertussis, hemophilus influenza, tetanus, hepatitis B, and polio immunogens.

F  
74. The kit of claim <sup>16</sup>59 where at least one of said

immunogens is a nonpediatric immunogen.

75. The kit of claim 74 wherein said nonpediatric immunogen is selected from the group consisting of anthrax, plague, encephalitis, meningococcal, pneumococcus, typhus, typhoid fever, streptococcus, staphylococcus, neisseria, lyme disease, cholera, E. coli, shigella, leishmania, leprosy, cytomegalovirus (CMV), respiratory syncytial, virus, Epstein Barr virus, herpes, influenza, parainfluenza, rotavirus, adenovirus, human immunodeficiency virus (HIV), hepatitis A, NonA NonB hepatitis, varicella, rabies, yellow fever, rabies, Japanese encephalitis, flavivirus, dengue, toxoplasmosis, coccidiomycosis, schistosomiasis, and malaria immunogens.

76. The kit of claim ~~59~~<sup>16</sup> in which at least one immunogen is selected from the group consisting of BCG, measles, mumps, rubella, diphtheria pertussis, hemophilus influenza, tetanus, hepatitis B, polio immunogens, anthrax, plague, encephalitis, meningococcal, meningitis, pneumococcus, pneumonia, typhus, typhoid fever, streptococcus, staphylococcus, neisseria, lyme disease, cholera, E. coli, shigella, leishmania, leprosy, cytomegalovirus (CMV), respiratory syncytial, virus, Epstein Barr virus, herpes, influenza, parainfluenza, rotavirus, adenovirus, human immunodeficiency virus (HIV), hepatitis A, NonA NonB hepatitis, varicella, rabies, yellow fever, rabies, Japanese encephalitis, flavivirus, dengue, toxoplasmosis, coccidiomycosis, schistosomiasis, and malaria immunogens.

77. The kit of claim ~~59~~<sup>16</sup> wherein at least one immunogen is selected from the group consisting of anthrax, plague, tetanus, pertussis, diphtheria, BCG, hemophilus influenza <sup>and</sup> smallpox immunogen.

78. The kit of claim 59 in which the disorder is an immune mediated cancer.

79. The kit of claim 59 in which the disorder is an autoimmune disease.

80. The kit of claim 79 in which the disease is a rheumatic disease or connective tissue disease.

82. The kit of claim 81 in which the disease is multiple sclerosis.

84. The kit of claim 59 in which the disorder is non-streptozotocin-induced diabetes.

86. The kit of claim 59, said kit further comprising instructions for the use of an immunosuppressant to reduce the incidence or severity of chronic immune mediated disorder which might occur as a result of said administration of said immunogens in the absence of said immunosuppressant.

88. The kit of claim 86 where said immunosuppressant is a glucocorticoid or a substance which induces the release of a glucocorticoid hormone. 16

90. The kit of claim <sup>16</sup> 39 in which the disorder is one which develops at least one year after a vaccination.

92. The kit of claim ~~59~~ wherein at least one immunogen is a bacterial immunogen.

8